

REMARKS

Applicant thanks the Examiner and the Examiner's supervisor, Mr. John Weiss, for telephone interviews granted June 29, 1999. In particular, Applicant sincerely appreciates Mr. Weiss's agreement to go above and beyond the ordinary to fully consider the amendments and arguments presented herein. With the understanding that the Office will make every effort to advance the prosecution of the above-captioned application, either to issue or appeal, Applicant now presents its fully developed arguments on the merits of the case notwithstanding the finality of the Office Action. In light of the following, Applicant respectfully requests full reconsideration, withdrawal of the final rejections and allowance of the claims.

Claim 8 stands rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Specifically, claim 1 failed to provide antecedent basis for the recitation, within claim 8, of "the dressing." Applicant has amended claim 8 to recite the inclusion of a dressing. Claim 8 has also been amended to ensure clear antecedent basis for the foam, also recited therein. Applicant submits that these amendments cure any deficiency within claim 8 as may have existed under §112; withdrawal of the rejection is therefore respectfully requested.

Claims 1 through 3 and 5 through 8 stand rejected under 35 USC §103(a) as being unpatentable over PCT publication No. WO 93/09736 published May 27, 1993 on behalf of Kuntz *et al.* ("Kuntz") in view of U.S. patent No. 4,402,687 issued September 6, 1983 to Denty *et al.* ("Denty"). Claims 4 and 9 through 11 stand rejected under 35 USC §103(a) as being unpatentable over Kuntz in view of Denty and U.S. patent No. 4,631,061 issued December 23, 1986 to Martin ("Martin"). Claim 12 stands rejected under 35 USC §103(a) as being unpatentable over Kuntz in view of Denty, Martin and U.S. patent No. 4,605,400 issued August 12, 1986 to Kurtz *et al.* ("Kurtz"). Claims 14 and 15 stand rejected under 35 USC §103(a) as being unpatentable over U.S. patent No. 4,460,361 issued July 17, 1984 to Nichols ("Nichols") in view of U.S. patent No. 3,804,090 issued April 16, 1974 to Holbrook ("Holbrook"). Claim 15 stands rejected under 35 USC §103(a) as being unpatentable over Nichols in view of Holbrook and

U.S. patent No. 5,234,419 issued August 10, 1993 to Bryant *et al.* ("Bryant"). For the reasons set forth herein, Applicant respectfully traverses each said rejection.

It is long established that the analysis of obviousness rests on several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the invention as claimed; (3) the level of ordinary skill in the art; and (4) the objective evidence of non-obviousness. The first three enumerated inquiries, often called the primary considerations, must be followed by the Patent and Trademark Office in meeting its initial burden of establishing a *prima facie* case of obviousness, i.e. a showing of the lack of a novel, non-obvious functional relationship. The last inquiry, into the secondary considerations, may be of use in rebutting such a *prima facie* case. Because, however, the burden of coming forth with rebuttal evidence only shifts to the applicant after the Office has established a *prima facie* case of obviousness, when the cited references fail to establish such a case the rejection is improper and, without more, the applicant is entitled to grant of the patent.

Furthermore, in determining the scope and content of the prior art for purposes of the obviousness determination, only the "pertinent" or "analogous" art is properly considered. Prior art is considered analogous if it is from the same field as the inventor's endeavor, regardless of the problem addressed, or if not from the same field of endeavor, if it is reasonably pertinent to the particular problem with which the inventor is involved. "Reasonably pertinent" is resolved by determining whether the inventor would have been motivated to consider the art in resolving his or her own problem. *See generally In re Clay*, 966 F.2d 656 (Fed. Cir. 1992) (setting forth presently followed rule of law with respect to scope of prior art properly considered in making obviousness determination). On the rule of *Clay*, Applicant respectfully disagrees with the Examiner's apparently continuing proposition that "the fact that Kuntz ... [discloses a] urine collecting [device] is irrelevant since the claimed structure is present." *See Office Action*, ¶9 (June 16, 1997). While such a proposition may have some applicability with respect to anticipation, *see e.g. In re Schreiber*, 1997 WL 656242, 3 (Fed. Cir. 1997) (new intended use for old product does not defeat finding of anticipation) and *In re Spada*, 911 F.2d 705,708 (Fed. Cir. 1990) ("[t]he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from

the prior art, can not impart patentability to claims to the known composition.”), it is simply not the law with respect to obviousness. *See Clay*, 966 F.2d 656; *see also Schreiber* 1997 WL 656242, 9 (Newman, J. dissenting) (new use for anticipated product could be claimed as non-anticipated method).

None of Applicant’s claims stand rejected as anticipated by Kuntz. Therefore, contrary to the position taken by the Office, the subject problem as addressed by Kuntz is intrinsically pertinent to the question of whether Applicant’s claims are patentable over Kuntz, or any combination of references including Kuntz. Because, as will be clearly established herein, Kuntz is neither analogous nor reasonably pertinent to the invention as claimed by Applicant, Kuntz cannot be cited against Applicant’s claims under 35 USC §103(a). To do so would be to completely disregard the statutory nature of the obviousness determination, which in no uncertain terms mandates that the determination be made from the perspective of “a person having ordinary skill in the art to which [the invention] pertains.” 35 USC §103(a).

Applicant discloses, and claims, a therapeutic combination for promoting wound healing in mammals. In at least the embodiment as recited in claim 1, this combination comprises a combination of elements directed toward the application of negative pressure into the wound site for drawing fluids therefrom, whereafter the fluids may be safely stored within a canister without risk for contamination of the greater combination of elements. In stark contrast, and as urged by Applicant in a previous reply¹, Kuntz is directed toward a urine collecting device. Clearly, Kuntz derives from an art nonanalogous that of Applicant. As to whether Kuntz is reasonably pertinent to the problem Applicant was trying to solve, so that Applicant may have been motivated to consider it in resolving Applicant’s own problem, *Clay* is again instructive.

In *Clay*, the invention concerned a process for storing refined liquid hydrocarbon product in a storage tank having a dead volume between the tank bottom and its outlet port. *Clay*, 966 F.2d at 657-58.

¹ Applicant notes that the Examiner has taken the position that Applicant’s arguments raise new issues. Advisory Action (June 8, 1998). While Applicant will now further develop some arguments in light of Mr. Weiss’s kind agreement to fully consider the merits of this case, the Examiner’s previous assertion is not correct. Applicant argued the nonanalogous nature of Kuntz as early as March 10, 1997. The present arguments merely expound upon and clarify the issues previously raised. Full consideration, notwithstanding Mr. Weiss’s agreement, is therefore respectfully requested.

Clay found the solution to his problem in placing a gelatin solution in the tank's dead volume. *Id.* In rejecting Clay's claims, the Patent and Trademark Office cited a patent to Sydansk disclosing a process for reducing the permeability of hydrocarbon-bearing formations and thus improving oil production, using a gel similar to that used by Clay. *Id.* at 658. In finding the patent to Sydansk neither analogous nor pertinent to Clay's invention, and on that ground overruling the Board, the Federal Circuit reasoned as follows:

Sydansk's gel treatment of underground formations functions to fill anomalies so as to improve flow profiles and sweep efficiencies of injection and production fluids through a formation, while Clay's gel functions to displace liquid product from the dead volume of a storage tank. Sydansk is concerned with plugging formation anomalies so that fluid is subsequently diverted by the gel into the formation matrix, thereby forcing bypassed oil contained in the matrix toward a production well. Sydansk is faced with the problem of recovering oil from rock, *i.e.*, from a matrix which is porous, permeable sedimentary rock of a subterranean formation where water has channeled through formation anomalies and bypassed oil present in the matrix. Such a problem is not reasonably pertinent to the particular problem with which Clay was involved – preventing loss of stored product to dead volume while preventing contamination of such product. Moreover, the subterranean formation of Sydansk is not structurally similar to, does not operate under the same temperature and pressure as, and does not function like Clay's storage tanks.

A person of ordinary skill in the art would not reasonably have expected to solve the problem of dead volume in tanks for storing refined petroleum by considering a reference dealing with plugging underground formation anomalies.

Id. at 659-60 (citations omitted).

With the perspective of *Clay*, it is clear that one of ordinary skill in the art of wound healing, where sterile conditions are critical to the prevention of potentially deadly infection, would never look to a urine collecting device for guidance. Applicant does acknowledge that many of the structures depicted in the figures of Kuntz resemble at least some of the structures recited in Applicant's claims. This is of no relevance, however, in considering whether there existed in the prior art a motivation for Applicant to consider the art of Kuntz in attempting to solve the problems of wound healing. In fact, absent the benefit of that knowledge imparted through Applicant's own claims, no relationship has been shown between the disclosure of Kuntz and the art of wound healing.

Applicant notes the Examiner's assertion that "attacking the primary reference by stating that it is non-analogous to the problem applicant is solving ... is improper and non-persuasive." Advisory Action

(June 8, 1998). The Examiner bases this assertion upon a further assertion that the primary reference may not be attacked for being non-analogous absent an attack upon the entire combination of cited references. No such rule of law exists. To maintain otherwise is tantamount to arguing that non-analogous art can somehow be transformed into analogous art simply by citing it in combination with other analogous art. Careful reconsideration of the Examiner's incorrect position is respectfully requested. Kuntz is neither analogous nor pertinent to the invention as claimed; its exclusion as a reference is therefore respectfully requested.

The nonanalogous nature of Kuntz becomes even more clear when considering the propriety of the rejection under the traditional standard for finding obviousness. Upon considering whether one of ordinary skill in the art would have been motivated to combine the structure of Kuntz with the bacterial filter of Denty, several points come immediately to mind. First, Kuntz has not been shown to be adapted for use in a sterile environment. As a result, there has been shown no motivation to protect the pump of Kuntz. Additionally, it is noted that the bacterial filter of Denty is adapted to prevent contamination of the contained fluid through an air vent. In other words, Denty simply discloses the use of a bacterial filter for a wholly unrelated purpose. In essence, the Examiner has simply located a bacterial filter in a reference that looks like the bacterial filter recited in Applicant's claims. In so doing, it is clear that either (1) the Examiner is performing impermissible hindsight reconstruction or (2) the Examiner misapprehends the claims. Based upon the Examiner's statement that one of ordinary skill in the art might be motivated to "provide the system of Kuntz with a bacterial filter as disclosed by Denty so that harmful bacteria is prevented from ... *entering the collection vessel from the vacuum pump*," Office Action, ¶3 (June 23, 1999) (emphasis added), it is apparent that the latter may be the case. No one of skill in the art is of the least concern that the collected wound fluids might be contaminated through the pump or otherwise. This motivational statement is clearly conjecture, unsupported by the facts or the prior art. Absent a proper showing, therefore, withdrawal of the rejection is respectfully requested.

As to the rejection of claims 14 and 15, Applicant notes that no combination of cited references teaches or suggests the combination, as recited in claim 14, of a molded plastic container with a deflector,

a bacterial filter and an anti-foaming substance within a chamber of the molded plastic container. The recited deflector diverts fluid towards the bottom of the container, away from an outlet, which incorporates the filter. This sub-combination goes far to ensure the remainder of the therapeutic wound healing combination is not contaminated with potentially infectious, and generally regarded as bio-hazardous, wound fluids. These elements, among others, being neither taught nor suggested in any combination of the references, claims 14 and 15 cannot be rendered obvious thereby. Withdrawal of each rejection is therefore respectfully requested.²

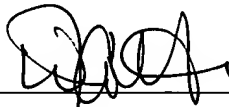
Notwithstanding any argument presented herein, Applicant has taken this opportunity to amend claim 1 for clarity, emphasizing the invention's character as a wound healing therapeutic combination. Claim 1 and other claims have also been amended for grammatical clarity. No new matter has been added. Entry of each amendment is therefore respectfully requested.

In light of all the foregoing, Applicant respectfully requests reconsideration and allowance of the claims and passage to issue of this present application. In the event that the Examiner finds some ground for non-entry of all or part of this reply after final, Applicant respectfully requests indication that any non-entered portion will be entered upon taking of appeal.

Respectfully submitted,

Dated: 08/23/99

WAYNE J. COLTON, INC.
The Milam Building Suite 1108
115 East Travis Street.
San Antonio, Texas 78205
Telephone: 210 222 8455
Telecopier: 210 222 8445



Wayne J. Colton
Agent for Applicant
Registration No. 40,962

² Applicant notes the Examiner's comment that the arguments concerning claims 14 and 15 are so vague as to bar consideration. Advisory Action (June 8, 1998). Applicant respectfully asserts, however, that the arguments, which are remade verbatim, are in the precise format required under *Graham*. The Examiner has failed to point to any motivation in the prior art to create the combination as recited by Applicant, much less shown such a motivation as would give rise to a reasonable expectation of success. The rejection thus being improper, withdrawal is respectfully requested.